



**TERMINAL DISCLAIMER TO OBIVATE A DOUBLE PATENTING  
REJECTION OVER A "PRIOR" PATENT**

Docket Number (Optional)  
PRJ-006CN

In re Application of: **Danny LEWIS et al.**

Application No.: **10/766106-Conf. #2190**

Filed: **January 27, 2004**

For: **METHODS AND COMPOSITIONS FOR ENHANCED DELIVERY OF BIOACTIVE MOLECULES**

The owner\*, **PR PHARMACEUTICALS, INC.**, of **100** percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent No. 6706289B2** as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

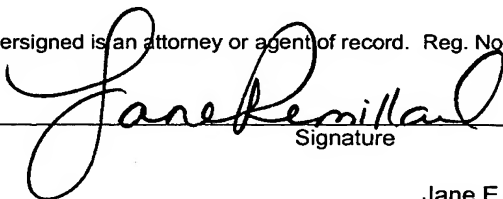
- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney or agent of record. Reg. No. **38,872**

  
Signature

**7/11/05**  
Date

**Jane E. Remillard, Esq.**  
Typed or printed name

**617-227-7400**  
Telephone Number

- ☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

\*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).  
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

07/14/2005 SSITHIB1 00000017 120080 10766106  
02 FC:2814 65.00 DA

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV553869548US, in an envelope addressed to: MS Amendment, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: July 11, 2005

Signature:  (Jane E. Remillard)



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PTO/SB/96 (09-04)  
Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

**STATEMENT UNDER 37 CFR 3.73(b)**

Applicant/Patent Owner: Danny LEWIS et al.

Application No./Patent No.: 10/766106 Filed/Issue Date: January 27, 2004

Entitled: METHODS AND COMPOSITIONS FOR ENHANCED DELIVERY OF BIOACTIVE MOLECULES

PR PHARMACEUTICALS, INC., a Corporation  
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or  
2. ☐ an assignee of less than the entire right, title and interest.

The extent (by percentage) of its ownership interest is \_\_\_\_\_ %

in the patent application/patent identified above by virtue of either:

- A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 012765, Frame 0331-33, or for which a copy thereof is attached.

OR

- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the United States Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.
2. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the United States Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.
3. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the United States Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☐ Copies of assignments or other documents in the chain of title are attached.  
[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Jane Remillard  
Signature

7/11/05  
Date

Jane E. Remillard, Esq.  
Printed or Typed Name

617-227-7400  
Telephone Number

Attorney of Record  
Title

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV553869548US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: July 11, 2005

Signature

Jane Remillard

(Jane E. Remillard)